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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	10577607
Filing Date	2006-04-27
First Named Inventor	W. Charles O'Neill
Art Unit	1619
Examiner Name	Tigabu Kassa
Attorney Docket Number	050508-1400

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	1	O'NEILL, W. CHARLES et al. Treatment with pyrophosphate inhibits uremic vascular calcification. Kidney International 2011; 79: 512-517. USA.	☐
	2	RUSSEL RGG et al. Pyrophosphate and diphosphates in calcium metabolism and their possible role in renal failure. Archives of Internal Medicine 1969; 124: 571-575. Switzerland.	☐
	3	MEYER JL. Can biological calcification occur in the presence of pyrophosphate? Archives of Biochemistry and Biophysics 1984; 231: 1-8. USA.	☐
	4	FRANCIS MD et al. Diphosphonates inhibit formation of calcium phosphate crystals in vitro and pathological calcification in vivo. Science 1969; 165: 1264-1266. USA.	☐
	5	TERKELTAUB, RA. Inorganic pyrophosphate generation and disposition in pathophysiology. American Journal of Physiology Cell Physiology 2001; 281: C1-C11. USA.	☐
	6	RUTSCH F et al. PC-1 nucleoside triphosphate pyrophosphohydrolase deficiency in idiopathic infantile arterial calcification. American Journal of Pathology 2001; 158: 543-554. USA.	☐
	7	GODING JW et al. Ecto-phosphodiesterase/pyrophosphate of lymphocytes and non-lymphoid cells; structure and function of the PC-1 family. Immunological Reviews 1998; 161: 11-26. Denmark.	☐
	8	O'NEILL WC et al. Plasma pyrophosphate and vascular calcification in chronic kidney disease. Nephrology Dialysis Transplantation 2010; 25: 187-191. England.	☐
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	11	LOMASHVILI KA et al. Effect of bisphosphates on vascular calcification and bone metabolism in experimental renal failure. Kidney International 2009; 75: 617-625. USA.	☐

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	12	MURSHED M et al. Unique coexpression in osteoblasts of broadly expressed genes accounts for the spatial restriction of ECM mineralization to bone. Genes & Development 2005; 19: 1093-1104. USA.	☐
	13	FEDDE KN et al. Alkaline phosphatase knock-out mice recapitulate the metabolic and skeletal defects of infantile hypophosphatasia. Journal of Bone and Mineral Research 1999; 14: 2015-2026. USA.	☐
	14	NEVEN E et al. Endochondral bone formation is involved in media calcification in rats and in men. Kidney International 2007; 72: 574-581. USA.	☐
	15	HENLEY C et al. 1,25 Dihydroxyvitamin D3 but not cinacalcet HCl (Sensipar/Mimpara) treatment mediates aortic calcification in a rat model of secondary hyperparathyroidism. Nephrology Dialysis Transplanation 2005; 20: 1370-1377. England.	☐
	16	MIZOBUCHI M et al. Differential effects of vitamin D receptor activators on vascular calcification in uremic rats. Kidney International 2007; 72: 709-715. USA.	☐
	17	CARDUS A et al. Differential effects of vitamin D analogs on vascular calcification. Journal of Bone and Mineral Research 2007; 22: 860-866. USA.	☐
	18	YOKOZAWA T et al. Animal model of adenine-induced chronic renal failure in rats. Nephron 1986; 44: 230-234. Japan.	☐
	19	OKADA H et al. Reversibility of adenine-induced renal failure in rats. Clinical and Experimental Nephrology 199; 3: 82-88. Japan.	☐
	20	MOOREHEAD W et al. 2-amino-2-methyl-1-propanol as the alkalizing agent in an improved continuous-flow cresolphthalein complexone procedure for calcium in serum. Clincial Chemistry 1974; 20: 1458-1460. USA.	☐
	21	MALLUCHE H et al. A new semiautomatic method for quantitative static and dynamic bone histology. Calcified Tissue International 1982; 34:439-448. USA.	☐
	22	MANAKA RC et al. A program package for quantitative analysis of histologic structure and remodeling dynamics of bone. Computer Programs in Biomedicine 1981; 13: 191-202. USA.	☐

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	23	COGAN EB et al., A robotics-based automated assay for inorganic and organic phosphates, Anal Biochem 1999; 271: 29-35. USA	☐

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	Cynthia J. Lee	Date (YYYY-MM-DD)	2011-11-28
Name/Print	Cynthia J. Lee	Registration Number	46,033

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**